

ORIGINAL ARTICLE

Clinical experiences of dynamic stabilizers: Dynesys and Dynesys top loading system for lumbar spine degenerative disease



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Abstract Dynesys (Dynamic Neutralization System) was designed to overcome the shortcomings of fusion. The Dynesys top loading (DTL) system is a new alternative Dynesys system that can be applied via a minimally invasive procedure. This study aimed to ascertain whether DTL is a suitable device for motion preservation and prevention of instability, and to compare the clinical and radiological outcomes between DTL and Dynesys. In this study, 12 patients were treated with Dynesys and 21 patients were treated with DTL. Back and leg pain were evaluated using the visual analog scale. The Oswestry Disability Index was used to evaluate the patients' function. Range of motion (ROM) at the operative level and for the whole lumbar spine was measured pre- and postoperatively. The length of wound, blood loss, length of hospital stay, and operation duration were also compared. All patients were followed up for 12–76 months. Scores on the visual analog scale and Oswestry Disability Index were significantly improved postoperatively. The median ROM of the whole spine and index level ROM in all patients showed 12.5% and 79.6% loss, respectively. The DTL group exhibited significantly better results in terms of blood loss, wound length, and operation duration, in addition to early ambulation. In conclusion, Dynesys and DTL are semirigid fixation systems that can significantly improve clinical symptoms and signs. Our results suggested that DTL was better than Dynesys as a result of it being a minimally invasive procedure. However, further study with large sample sizes and longer follow-up durations is required to validate the effects of these dynamic stabilizers.

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Introduction

The degenerative disease of the lumbar spine involves the disks, vertebral bodies, and facet joints, and results in painful intervertebral instability. When degenerative change occurs in a later phase, surgery may be necessary for stabilization, decompression, and correction of deformity [1]. Spinal fusion is the traditional treatment in the later phases of spinal degenerative disease [2]. Unfortunately, spinal fusion surgery is associated with increased stress and strain at the adjacent motion segments [3,4], which can lead to loss of lumbar spinal mobility, pseudarthrosis, chronic lower back pain, accelerated degeneration of adjacent segments, and other related symptoms [5,6]. Some motion-preservation surgeries, including artificial nucleus replacement, artificial disk replacement, and posterior dynamic stabilization, have been developed to overcome fusion in the management of degenerative conditions of the lumbar spine [7]. The Dynamic Neutralization System (Dynesys) was first introduced by Dubois and colleagues [8], and was used in France from 1994 onward. Since then, Dynesys has remained the most widely implanted posterior nonfusion pedicle screw system [9]. A new alternative system—the Dynesys top loading (DTL) system—was introduced in 2011. This system is designed for use with 1.6-mm K-wires with blunt ends, a cannulated bone awl, a pedicle probe, and cannulated screws to fit the minimally invasive surgery (MIS) requirement. In this study, we compared the effectiveness of the Dynesys and DTL systems for the treatment of degenerative lumbar spine disease by assessing the clinical outcomes and radiological findings, and described the employment of the DTL system through a modified Wiltse approach.

Methods

Patients

This retrospective study evaluated the outcomes of patients undergoing surgery with Dynesys or the DTL system. Twelve patients with lumbar degenerative disease, including spinal stenosis and/or herniated intervertebral disk (HIVD), were treated with decompression surgery and Dynesys from August 2008 to September 2011. Twenty-one patients with the same diseases were treated using the DTL system between April 2013 and June 2014 at our center by one surgeon (C.J.C.). There were 20 male and 13 female patients, with a slight male predominance. The median age of the patients was 51 years (range, 41–59 years). The diagnoses included degenerative spinal stenosis (14/30), severe spinal stenosis with HIVD (14/33), huge intervertebral herniated disk (4/33), or recurrent HIVD (1/33). In most patients, three levels were involved (25/33); in six patients, two levels were involved; and in two patients, four levels were involved. The inclusion criteria for implantation were younger patients, severe spinal stenosis with/without HIVD, two-level HIVD, no defined instability with joint degeneration, and no osteoporosis (bone mineral density was checked in patients older than 60 years). The exclusion criteria in our study included elderly patients with osteoporosis, a defined unstable condition, and simple HIVD. All

patients underwent routine preoperative examinations, including dynamic lumbar spine X-ray, plain abdomen X-ray, lumbar spine magnetic resonance imaging (MRI), and postoperative dynamic X-ray. The radiological images and medical records were reviewed. The Oswestry Disability Index (ODI) and visual analog scale (VAS) were applied to quantify pain and function of patients, measured prior to and after the surgery, by one independent nurse specialist under the supervision of the attending physician.

Surgical procedure

Dynesys

Patients were operated on under general anesthesia in the prone position with adequate cushioning, and a fluoroscope was used routinely to locate the level of surgery. After midline incision and subperiosteal dissection of the erector spine muscles, the affected segment was exposed. Standard lumbar total laminectomies with foraminotomies/microdisectomy were performed for direct posterior decompression at the indicated levels. After adequate decompression, insertion of the Dynesys pedicle screws was carried out after identifying the facet joints and transverse processes, and their correct positions were confirmed by intraoperative fluoroscope imaging. Because the devices are designed for dynamic stability, facet joints and capsule preservation are very important. A drainage catheter was placed in the epidural space and the wound was closed in layers.

DTL system

Under general anesthesia, patients were placed prone in the natural lumbar lordosis position. A lateral view of the C-arm was obtained to confirm the level of surgery, such that the target object was directly perpendicular to the ground. Next, the C-arm was changed to the anteroposterior view to determine the positioning of the skin incision. The incision was made from the highest to the lowest pedicle level, and ranged from 4 cm for two levels to 7 cm for three levels. After midline incision, unilateral microscopic laminotomy or laminoforaminotomy, including decompression of the opposite side, with or without discectomy were performed to achieve adequate decompression. The midline fascia was closed with 1–0 vicryl without drainage. A generous subdermal dissection through the same skin incision was performed. This allowed adequate skin retraction for pinning of the target needle to the pedicle through the paramedian fascia layer under C-arm guidance. The DTL screws were then implanted routinely under the guidance of the guide pin. Next, spacers and cords were placed through the top loading system to connect the screws without muscle distraction (Figures 1A–1D). This alternative method was named the modified Wiltse approach (Figure 1E).

Case illustration

Dynesys

A 42-year-old patient who had suffered from lower back pain with radiation pain to the bilateral lower legs for several years was treated. Intermittent claudication worsened after medical and physical therapy for 6 months. An L-

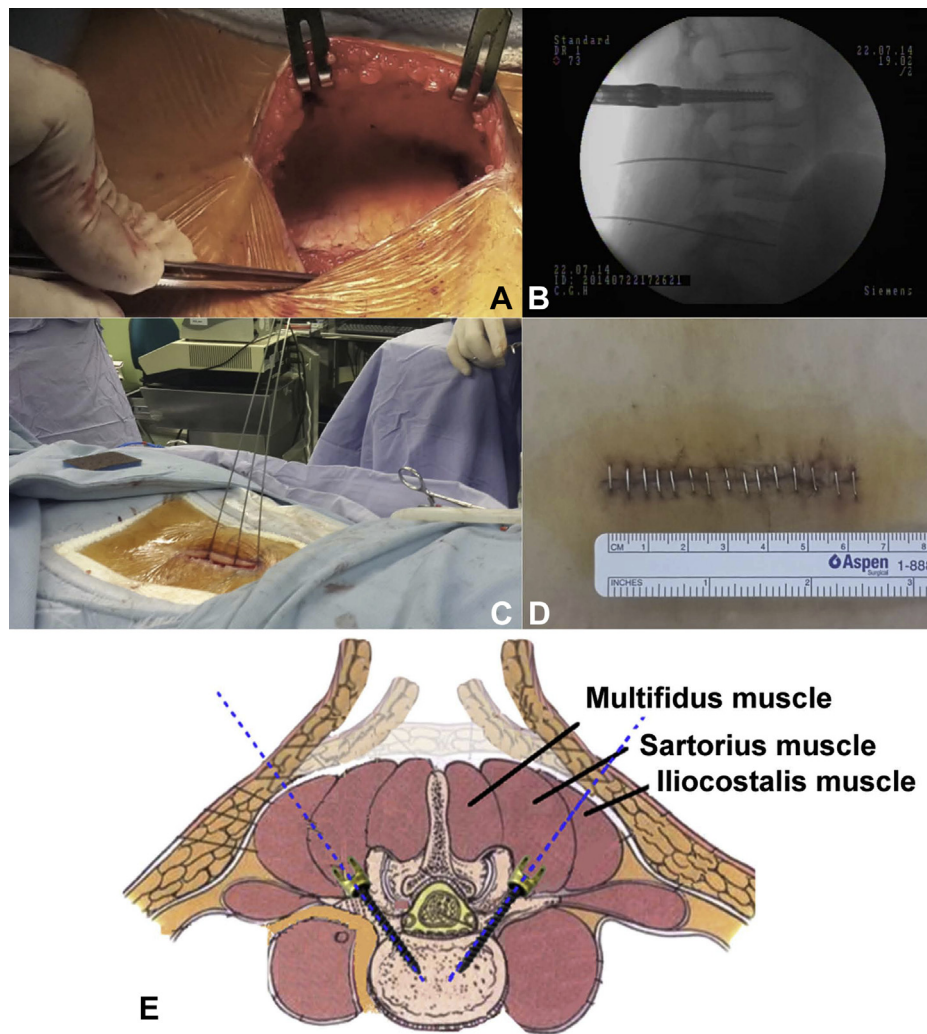


Figure 1. Surgical procedure of Dynesys top loading (DTL). (A) Generous subdermal dissection was performed through the same skin incision. (B, C) Target needle was inserted into the pedicle through the paramedian fascia layer under C-arm guidance, and DTL screws were then implanted routinely under the guidance of the guide pin. (D) One 6-cm wound was required for three-level DTL insertion without drainage. (E) Modified Wiltse approach.

spine MRI and X-ray were performed, and revealed lumbar spondylosis and severe lumbar stenosis (Figure 2A). Because of the structural stenosis and progressive symptoms, laminectomy was indicated. In consideration of the patient's young age and the possibility of iatrogenic instability after surgery, a traditional total laminectomy with Dynesys implantation was carried out in June 2009 (Figure 2B). After 2 years of follow-up, radiological images showed adequate decompression for lumbar stenosis, and no degeneration or instability was noted over the adjacent levels (Figure 2C). Clinically, other than occasional mild back soreness, the patient was satisfied with the outcome.

DTL system

A 54-year-old male patient had lower back pain and intermittent claudication for several years, and right sciatic pain occurred prior to his visit to our department. The clinical symptoms and signs were aggressive after the conservative treatment. Lumbar spine X-ray revealed spondylotic change with a narrowed intervertebral space, and L-spine MRI

showed bulging and right extraforaminal protrusion of the L4-5-S1 disk, causing severe spinal canal and bilateral neuroforaminal stenosis (Figures 3A–3E). Because of HIVD with severe spinal stenosis and disk degenerative changes, a unilateral hemilaminectomy with microdiscectomy was performed to achieve adequate decompression, and DTL was applied for the L4-5-S1 level to provide stability through the modified Wiltse approach described above. The length of the wound was 6 cm, and the patient was able to walk well with a soft brace the day after the surgery; he was discharged 4 days after the surgery. The clinical functional and radiological outcomes were very good, and adequate decompression was observed on the follow-up MRI (Figures 3F–3J).

Study measures

The study measures were obtained prior to the surgery, at 3 months, 6 months, and 12 months postoperatively, and at the final follow-up, including clinical outcomes and

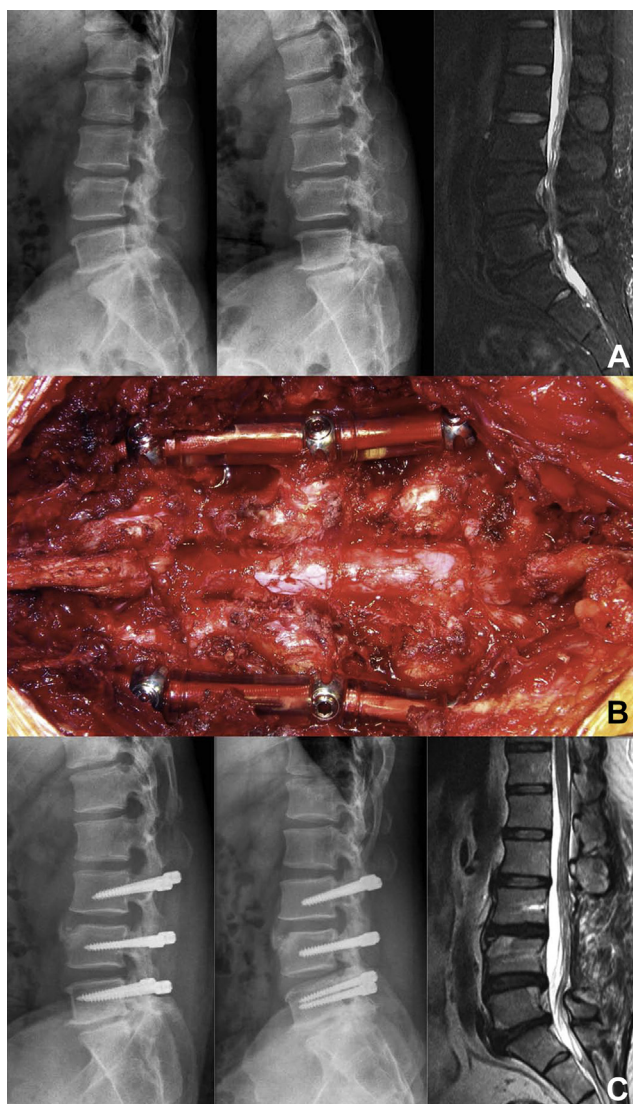


Figure 2. Example of a patient who underwent Dynesys implantation. (A) L-spine magnetic resonance imaging (MRI) and lumbar spine X-ray were performed, and revealed lumbar spondylosis and severe lumbar stenosis. (B) Intraoperative imaging showed the traditional total laminectomy and implantation of Dynesys with preservation of all facet joints. (C) At the 2-year follow-up point, the radiological images showed adequate decompression for lumbar stenosis, and no degeneration or instability was noted over the adjacent levels.

radiographic results. Perioperative data such as duration of surgery and blood loss were recorded, and details of perioperative complications, wound length, and length of hospital stay were also collected. Blood loss, wound length, operation duration, VAS scores of the back and legs, and the ODI were used to evaluate the patients' functional outcome. Radiographic assessment was performed from flexion–extension radiographic views of the lumbar spine. The parameters were the angles of the range of motion (ROM) of the whole spine and the index levels elucidated using flexion–extension radiography. The angle was measured in flexion or extension preoperatively and postoperatively at 3 months, 6 months, and 12 months. The

changes of ROM in the operated segment (L4–L5) and the whole spine (L1–S1) were defined as the difference between the preoperative and postoperative ROM angles. Radiographs of all patients were obtained twice by the same research nurse, and the mean value for each parameter was recorded.

Statistical analysis

Data were expressed as the median (25th–75th percentile). Statistical analysis was performed using a statistical program (SPSS version 13.0; SPSS Inc., Chicago, IL, USA). The clinical and radiologic data were analyzed using the paired-samples Mann–Whitney *U* test. A *p* value < 0.05 was considered statistically significant.

Results

All patients were followed up for 12–76 months (mean, 14.2 months), and the mean age of all patients was 51 years (range, 41–59 years). There were no significant differences in age, sex, and hospital stay duration between the two groups. However, there were significant differences in terms of blood loss, wound length, and operation duration between the groups (*p* < 0.01; Table 1). Clinically, patients in the DTL group were able to ambulate by postoperative Day 2. By contrast, it took 4–6 days for patients in the Dynesys group to mobilize. No major complications occurred during the surgeries. There were four broken screws out of a total of 190 screws, and no screw loosening was noted. No development of unstable conditions occurred, and none of the cases needed revision surgery in our study.

Clinical results

Functional outcomes including ODI score and VAS scores of the legs and back were significantly improved at 1 month, 3 months, 6 months, and 12 months postoperatively in both groups (Figure 4). The ODI scores in the DTL group at 1 month, 3 months, and 6 months postoperatively were better than those in the Dynesys group (*p* < 0.05; Figure 5).

Radiologic results

There were significant differences in the ROM at the operative level and for the whole spine between the DTL and Dynesys groups. The median ROM of the whole spine was 30.4° (21.5–42.4°) preoperatively and 26.6° (17.3–29.2°) 1 year postoperatively, with a 12.5% loss, in all patients. The ROM at the operative level was 13.9° (8.1–20.6°) preoperatively and 3.2° (1.2–7.9°) 1 year postoperatively, with a 76.9% loss (Table 2).

Interestingly, when looking at the whole lumbar spine ROM at the last follow-up (12 months postoperatively), different trends were observed in the two groups. The DTL group had a ROM that moved closer to the preoperative range, although no significant difference was found. By contrast, the Dynesys group had a decreasing ROM at each postoperative follow-up (Figure 6).

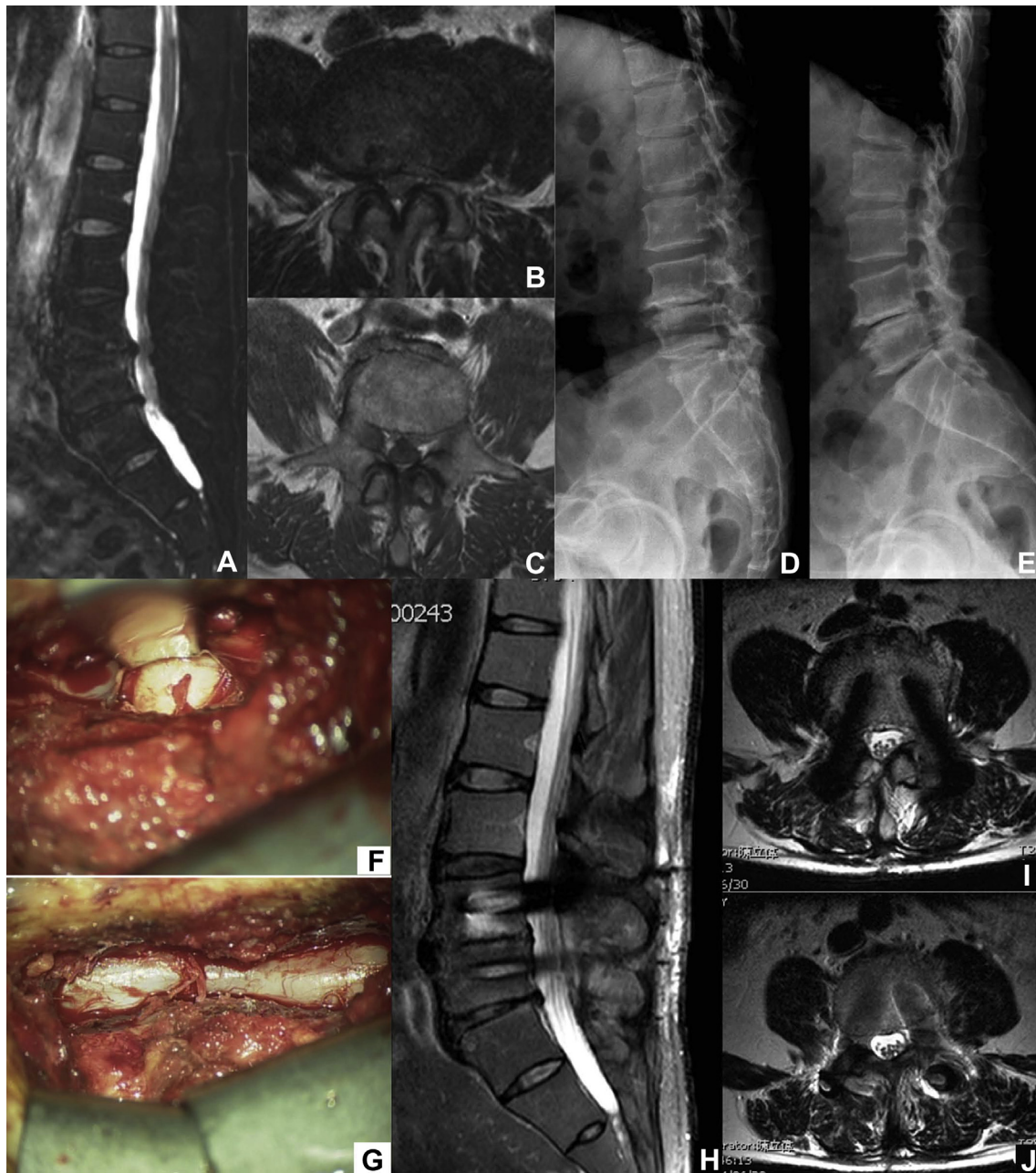


Figure 3. Example of a patient who underwent DTL implantation. (A–C) L-spine MRI showed bulging and R't extraforaminal protrusion of the L4-5–S1 disk with Modic type II endplate changes, causing severe spinal canal and bilateral neuroforaminal stenosis. (D, E) Dynamic view X-ray showed spondylotic change with spurs at the lumbar vertebrae and degenerative disk with a narrowed intervertebral space at the L4-5 and L5–S1 levels. (F) A herniated disk was noted. (G) Adequate decompression was achieved after unilateral hemilaminectomy with microdisctomy. (H–J) Follow-up MRI showed an enlarged spinal sac without neural compression in the sagittal and axial views. DTL = Dynesys top loading; MRI = magnetic resonance imaging.

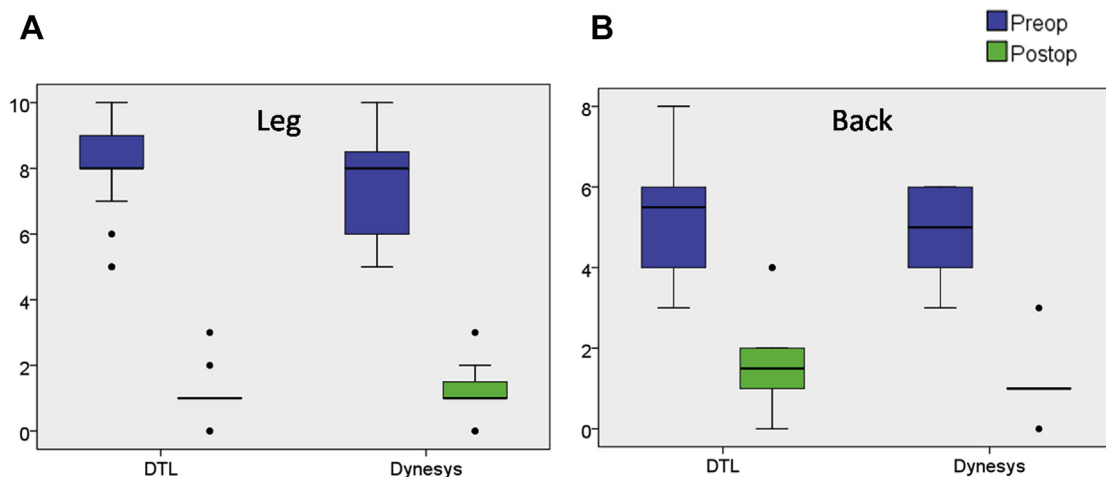
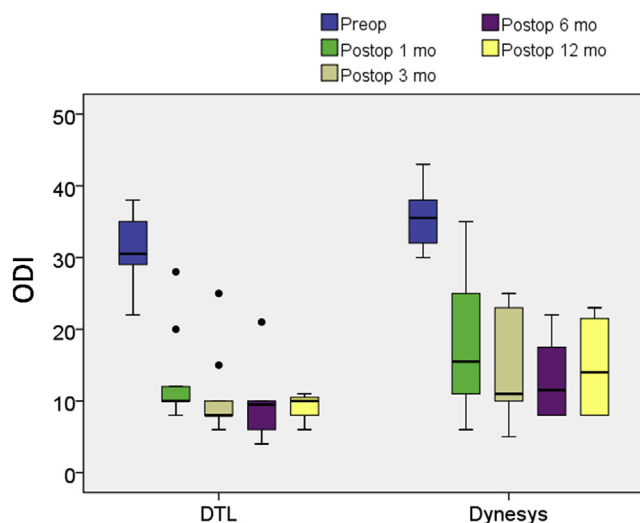
Discussion

Degenerative lumbar spine disorders are very common diseases and represent a complex pathology because of the natural aging process [5]. Most patients suffer from back pain with/without neurological deficits, and the severity of symptoms is proportional to the degree of degeneration. According to the theory of Kirkaldy-Willis and Farfan [10] published in 1982, the progressive process of lumbar spine

degeneration can be divided into three phases: (1) temporal dysfunction, (2) unstable phase, and (3) restabilization. In the early stages of lumbar degeneration, clinical symptoms may improve after conservative treatment. However, surgical treatment may be indicated when conservative treatment fails or when the degenerative change reaches a late phase. Spinal fusion is a conventional strategy for the treatment of patients with structural deformity, preoperative instability, or the possibility of postoperative iatrogenic

Table 1 Patient demographic and baseline data in the Dynesys top loading (DTL) and Dynesys groups.

| | DTL | Dynesys | <i>p</i> |
|------------------------------|---------------------|---------------------|----------|
| Sex (M/F) | 12/9 | 8/4 | 0.719 |
| Age (y) | 53.0 (40.0–59.0) | 48.5 (41.0–57.8) | 0.839 |
| Body mass index | 25.3 (23.6–27.6) | 30.3 (25.7–31.5) | 0.024 |
| Hospitalization duration (d) | 8.0 (7.0–12.5) | 11.5 (8.5–14.0) | 0.113 |
| Blood loss (mL) | 30.0 (20.0–50.0) | 250.0 (200.0–300.0) | <0.001 |
| Wound length (cm) | 6.0 (6.0–8.0) | 15.0 (13.5–15.0) | <0.001 |
| Operation duration (min) | 163.0 (146.0–170.0) | 207.5 (185.0–214.5) | <0.001 |

**Figure 4.** Visual analog scale (VAS) scores of (A) the legs and (B) the back were significantly improved at postoperative 1 month, 3 months, 6 months, and 12 months in both groups. Postop = postoperative; Preop = preoperative.**Figure 5.** Results of the Oswestry Disability Index (ODI) score in the Dynesys top loading (DTL) group at postoperative 1 month, 3 months, and 6 months were better than those in the Dynesys group. Postop = postoperative; Preop = preoperative.

instability. However, fusion has several potential disadvantages, such as sacrifice of motion of operative segments, pseudoarthrosis, infection, and implant failure [5,11,12]. The major problem is that rigid instrumentation and fusion

increase the mechanical stress on the adjacent segments, which may cause degenerative changes at motion segments caudal or/and cephalad to the fused segment. These changes may result in failed back syndrome, which requires additional surgery [13]. Several methods of spinal stabilization for achieving stability without rigid fusion have been developed, referred to as "dynamic stability" and "soft stability" [14]. Posterior nonfusion pedicle-screw-based stabilization is most commonly used for the purpose of achieving dynamic stability in spinal surgery [9]. The first instrument in common usage was the Graft ligament, introduced in the 1990s. Unfortunately, this design had several theoretical disadvantages, such as increasing lateral recess and foraminal narrowing with nerve root compression [9,15]. Additionally, some studies showed a poor outcome, and this procedure was not recommended [9].

Dynesys, a posterior nonfusion spinal fixation technique, was developed by the French scholar Gilles Dubois and his coworkers [8] in 1991, and was clinically introduced in 1994. In flexion, motion is controlled by tension on the band, whereas during extension the plastic cylindrical tubes act as a partially compressible spacer, thereby allowing limited extension [11,16]. Theoretically, this system can reduce the load on the disk in extension to avoid the problems seen in graft ligamentoplasty that result in posterior annulus-related compression [17].

In a biomechanical study, Schulte et al [18] proved that decompression in addition to the Dynesys system can better

Table 2 Range of motion (ROM) preoperatively and postoperatively.

| | Whole spine ROM | <i>p</i> | Index level ROM | <i>p</i> |
|---------------------|------------------|----------|-----------------|----------|
| Preoperative | 30.4 (21.5–42.4) | | 13.9 (8.1–20.6) | |
| Postoperative 1 mo | 15.5 (10.9–21.5) | <0.001 | 2.0 (–2.5–+3.3) | <0.001 |
| Postoperative 3 mo | 18.2 (15.3–26.1) | 0.001 | 3.8 (1.2–4.9) | <0.001 |
| Postoperative 6 mo | 22.2 (17.4–28.0) | 0.025 | 3.5 (0.4–5.7) | <0.001 |
| Postoperative 12 mo | 26.6 (17.3–29.2) | 0.003 | 3.2 (1.2–7.9) | <0.001 |
| Postoperative 24 mo | 19.8 (11.6–24.6) | 0.006 | 1.7 (–0.1–+8.4) | 0.004 |

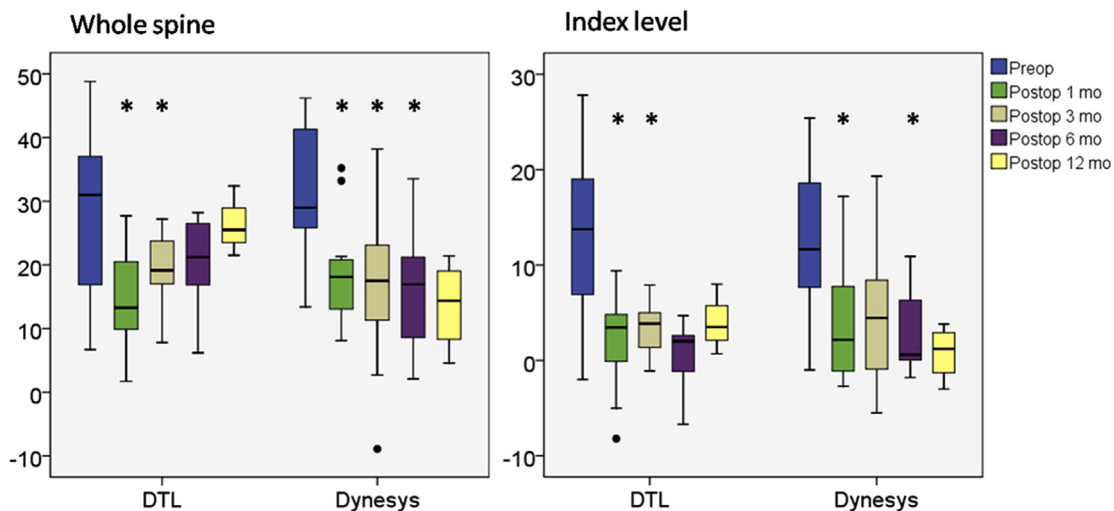


Figure 6. The Dynesys top loading (DTL) group had a range of motion (ROM) that moved closer to the preoperative range, although no significant difference was found. By contrast, the Dynesys group had a decreasing ROM at each follow-up point (* $p < 0.05$). Postop = postoperative; Preop = preoperative.

limit the flexion, extension, and lateral bending of a fixed segment, and can reduce the intervertebral disk pressure of the fixed segments remarkably without affecting the adjacent segments [19]. Some clinical studies have evaluated the effects of Dynesys. Very good results were noted in 83 patients treated with Dynesys in a multicenter trial conducted by Stoll et al [20], in which no broken screws were noted, implying that the device might reduce disk degeneration by reducing the load on the disks. Putzier et al [21] noted that Dynesys may stop further disk degenerative changes in a series of 49 patients undergoing microdiscectomy alone versus 35 patients undergoing microdiscectomy with the addition of Dynesys stabilization. Good outcomes with Dynesys were reported in 94 patients with a 2-year follow-up period by Bordes-Monmeneu et al [22], and they considered that Dynesys may be useful in that it incorporates the functionality concept as opposed to restricting movement. In addition, in recent studies, Yu et al [23] compared patients treated with Dynesys or posterior lumbar interbody fusion with a 3-year follow-up duration. They noted that the Dynesys patients had greater preservation of motion at the operative levels, as well as a larger total ROM, and the Dynesys group had a better outcome according to clinical evaluation. Another study by Yang et al [24] compared 30 patients who underwent treatment with Dynesys and 45 patients treated with posterior lumbar interbody fusion,

and found that Dynesys resulted in better patient outcomes.

However, in addition to the results of the above-mentioned studies, poor outcomes have also been reported. Grob et al [25] studied a series of 31 patients, in whom the reoperation rate was as high as 19%. They believe that the Dynesys system was not superior to posterior rigid fusion. In addition, four broken and two misplaced pedicle screws within a total of 224 screws implanted were noted in the study of Würgler-Hauri and coworkers [26] during a 1-year follow-up period. Other studies also showed that Dynesys led to similar or poorer outcomes to posterior lumbar interbody fusion [27–29].

Our results were similar to those reported in most published papers, in that the ODI score and VAS scores of the legs and back significantly improved after surgery in both groups. In our series, no patient with HIVD developed disk instability or recurrence. No complications occurred that required secondary surgery. Indeed, the implants provided immediate stabilization and preserved 70.5% of the whole lumbar spine ROM and 15.2% of the ROM at the treated levels at the 12-month follow-up point. Because no fusion procedure is performed, there are concerns regarding implant loosening or breakage. In our study, four screw breakages were noted in two patients, and no screw loosening was observed. Comparing our results to those published by Ko et al [1], the rate of implant breakage was

similar. No related clinical signs or symptoms occurred. All screws were broken inside the vertebral body, about one-third of the total length close to the screw head. We suspected that this may be due to the original design of Dynesys/DTL screws and metal fatigue. However, in terms of implant loosening, Ko et al [1] noted a high incidence (at a rate of 4.6% of the total number of screws; 17 of 368 screws), whereas we observed no loosening at all. This may be attributable to the difference in the average age of the patients, in that our patient group was much younger than that of Ko et al [1] (49.5 ± 10.4 years vs. 59.2 ± 11.65 years; range, 23–80 years vs. 22–67 years). Besides, all our S1 screws were bicortical. We also had a shorter period of follow-up as compared with the study of Ko et al [1]. A study by Kuo et al [30] also showed that loosening of screws was associated with an older patient age (> 45 years) and S1 involvement.

The standard techniques for exposing the lumbar posterior elements, which include stripping the multifidus muscles bilaterally, with subsequent wide retraction, have potentially serious consequences. Such dissection was often necessary during placement of Dynesys screws with traditional decompression. Our novel procedure, the modified Wiltse approach, uses a midline approach to achieve decompression, including discotomy, unilateral/bilateral laminotomy, and even total laminectomy. This approach is a familiar route for most spinal surgeons. In addition, this procedure facilitates placement of implants and reduces damage to muscles.

Based on our findings, both the DTL and Dynesys groups demonstrated similar radiological results as well as functional outcomes in terms of legs and back VAS score improvements. However, the patients in the DTL group showed significantly better results than those in the Dynesys group, with reductions in operation duration, blood loss volume, wound length, and postoperative ODI score. There was also a tendency toward progressive recovery of postoperative ROM of the whole spine.

In terms of the entire range of complications, a recent comprehensive review of the literature by Pham and colleagues [31] that included 21 studies and a total of 1166 patients indicated that the complication rate associated with the Dynesys system was fairly similar to that of lumbar fusion. Whether or not the DTL system also has a low complication rate requires further study.

In our opinion, the new DTL implant system is better than Dynesys because it offers the possibility of performing a minimally invasive procedure. Therefore, when a patient is suitable for dynamic stabilization, we suggest using DTL through a modified Wiltse approach rather than the traditional open approach. Based on the results of our study, DTL is more suitable for younger patients with severe spinal stenosis with or without HIVD, two-level HIVD, no defined instability with joint degeneration, and no osteoporosis. DTL is most beneficial in preventing iatrogenic instability in the decompressed spine and the degeneration cascade. However, there are also disadvantages of DTL, which include: (1) higher cost, and as the instruments are not covered by the National Health Insurance in Taiwan, patients need to shoulder this cost themselves; (2) because the nonfusion technique is used, screw loosening is likely before spontaneous fusion occurs.

The limitations of this study included the following. (1) The mean follow-up duration for the patients was only 14.2 months (range, 12–76 months), and a much longer follow-up period is necessary in order to determine the long-term clinical effects of Dynesys and DTL. (2) The number of patients was small, which may be the reason for the significant difference. (3) In order to minimize the variance, data were obtained from patients who underwent surgery performed by a single surgeon in our hospital. This might cause bias, and therefore further randomized controlled study in multiple medical centers should be conducted.

Decompression surgery has long been the gold standard for the treatment of lumbar spine stenosis. However, this may lead to instability at the index level because of the extensive excision of facet joints, laminae, and disks, and this instability has been considered to be the main concern in the conduction of decompression surgery without instrumentation.

Dynamic stabilization implants such as Dynesys/DTL have been designed to present a new option for the treatment of spinal diseases, rather than to replace rigid fixation fusion surgeries. They are most useful in preventing iatrogenic instability in the decompressed spine and the degeneration cascade. The most suitable indication for dynamic stabilization is a young patient who needs both adequate decompression and postoperative stability. Most importantly, there is a need for a prospective randomized study comparing decompression only and decompression plus Dynesys in order to understand the true value of dynamic stabilizers.

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